Ansell Perry

January 26, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 98N-0313
Surgeon's and Patient Examination Gloves; Reclassification

Dear Sir or Madam:

Ansell Healthcare Products Inc. ("Ansell"), a major manufacturer of medical gloves for the United States and international markets, submits these comments on the above referenced proposed rule published in the Federal Register of July 30, 1999 (64 Fed. Reg. 41710). The comment period on this proposal was extended to January 27, 2000 on October 28, 1999 (64 Fed. Reg. 58004).

Initially, Ansell wishes to express its support for the general intent of the proposed rule to reduce adverse health effects which may be associated with surgeon's and patient examination gloves and to cause these devices to be manufactured with lower amounts of powder and latex allergens which are feasible with superior technology and improvements in glove processing.

However, Ansell believes that many of the specific provisions of the proposed rule are not well-designed to accomplish these objectives, and that the agency should consider and adopt instead the positions developed by the American Society for Testing and Materials ("ASTM") and its Medical Glove Task Group, whose work has been supported by Ansell and other responsible manufacturers of medical gloves. ASTM's Task Group has worked a number of years with FDA representatives to develop recommended standards and test methods for medical gloves, which are directly relevant to the proposed rule. The failure of the proposal to consider this work and the proposal of recommended limits for powder and protein on medical gloves, which the agency knows, were considered rejected by the ASTM Task Group is unreasonable and should be corrected in the final rule. The agency should also carefully consider the comments of the Health Industry Manufacturers Association ("HIMA") which Ansell also supports. Ansell sets forth below its position on several issues raised by the proposal:

Basis for the Proposal

The proposed rule is based on FDA's assertion that the general controls applicable to medical devices under the Federal Food, Drug and Cosmetic Act are insufficient to provide reasonable assurance of safety and effectiveness for medical gloves, and that the proposed requirements as to latex protein and glove powder are intended to reduce adverse health effects associated with medical gloves. However, the adverse reactions related to medical gloves are not attributed to either powder or protein as such but to

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specific allergens, which may be found in latex protein. The role of powder as a carrier for allergens from latex, which may increase the potential for exposure to these allergens, is not well understood or scientifically documented. While lesser quantities of both latex protein and powder in medical gloves may be desirable, FDA in the proposal states:

> "The scientific data to define a quantitative relationship between respiratory allergic reactions and powder level on NL gloves are not available at this time."

64 Fed. Reg. at 41712. In the absence of this data, Ansell submits that there is no scientific basis for FDA to regulate the levels of powder or protein on gloves. Ansell believes any limitation should be on allergen levels, not protein levels. Nonetheless, Ansell does not oppose reclassification or the imposition of reasonable recommended limitations on powder and, on an interim basis, on protein levels because it believes that it is or soon will be within the capability of industry to meet such limits and because of the possibility that such limits will produce a health benefit.

A. Protein Level Limit for Latex Gloves

If FDA is committed, in the interim, to limit protein rather than allergen levels, Ansell opposes the recommended level in the proposal of 1200 micrograms per glove of extractable latex protein. Setting a protein level on a per glove basis is unreasonable because the amount of protein contained in gloves depends upon the surface area of the glove and the surface area of the glove varies significantly based on the size of the glove. This was recognized by the ASTM Medical Glove Task Group which specifically considered and rejected a per glove limitation on protein for this reason. FDA should change its recommended limit for protein to be consistent with that in the ASTM consensus standards for latex surgeon's gloves and patient examination gloves: 200 micrograms per square decimeter.

B. Powder Levels for Medical Gloves

1. Powder-free gloves. Ansell supports the recommended level of not more than two milligrams per glove for powder-free gloves. By the time it is implemented, this level will be consistent with the level recommended by ASTM standards for powder-free glove.

2. Powdered gloves. Ansell opposes the recommended powder level for powdered gloves of 120 milligrams per glove proposed by FDA. As with latex protein, the amount of powder on gloves depends on the surface area of the glove and differs significantly for different size gloves. Again, this was recognized by the ASTM Task Group which specifically rejected the concept that the recommended limit on powder be stated on a per glove label basis and decided that its recommended limit should be expressed in milligrams of powder per square decimeter. FDA similarly should express any recommended limit for powder on powdered gloves on this basis.

The recommended powder limit approved by ASTM for the surgical glove standard, based on Medical Glove Task Group recommendations, is 30 milligrams per square decimeter of the total surface area of the glove for the year after adoption, 20 milligrams for the following year and 15 milligrams thereafter. The recommended powder limit

approved for the ASTM three examination glove standards is 20 milligrams per square decimeter of the total surface area of the glove for the year after adoption, 15 milligrams for the following year and 10 milligrams thereafter. Each of these recommended limits takes into account the differences in glove size, because they are based on total surface area of the glove, and also considers the ability of glove manufactures to adjust their operations to meet these limitations. Ansell therefore recommends that FDA accept each of ASTM's recommendations on powder limits for powdered medical gloves and incorporate them into the final rule.

Ansell submits that the differing powder limits recommended by ASTM for surgeon's gloves and for patient examination gloves are appropriate because of the very significant differences in design between these two types of devices. Surgeon's gloves differ from examination gloves in that they are designed specifically to fit each hand and have opposable thumbs. They are also longer and differ in thickness from examination gloves, and are usually sized to the half size rather than merely small, medium and large as are examination gloves. Surgeon's gloves thus are designed to fit more snugly to the hand than are examination gloves. This closer fit provides better "feel" to the user for the delicate finger manipulations required in surgery. For these reasons, the amount of powder needed for surgeon's gloves significantly greatly than for examination gloves.

C. Labeling

FDA has proposed a number of changes in the labeling of medical gloves, which would require the re-labeling of virtually all medical gloves. This imposes a serious burden on Ansell and other glove manufacturers, especially since the company has just recently finished re-labeling all of its latex glove products to comply with the 1997 regulation requiring a caution statement on the label of all latex-containing medical devices. Ansell opposes a number of elements of the new labeling requirements and instead urges FDA to adopt the alternative approach being proposed by HIMA in its comments in this proceeding.

1. FDA Recommendations. FDA proposes that glove labels contain FDA recommendations as to the maximum amount of protein on latex gloves and the maximum amount of powder on powdered gloves. Ansell opposes both of these recommendations being required on glove labels not only because they would state recommended limits in inappropriate units, as discussed above, but also for two other reasons. First, a recommendation by FDA on a product label suggests to the user that there is a scientific basis for FDA making this recommendation. Since Ansell does not believe that such a scientific basis exists for either a protein or a powder limit, it opposes a requirement that these recommendations appear on the label of its products. Second, a recommendation in the name of FDA would be unacceptable in many foreign countries in which Ansell sells its gloves and would require separate labels for such sales and the attendant higher costs of maintaining two sets to labels for the same products.

2. Declaration of Protein and Powder Content. FDA also proposes that each latex glove be labeled with the specific amount of protein on that glove and each powdered glove be labeled with the specific amount of powder on that glove. Ansell opposes this requirement because it would lead to great confusion in the marketplace and provide less reputable marketers with an incentive to claim lower

protein or powder values than are supportable for their products. If specific protein and powder values were required to be declared, this would incorrectly imply that the lower numbers were more desirable or a safer product when the differences between the values for different products might be either insignificant or actually wrong based on the qualitative difference between latex proteins and their respective ability or inability to elicit allergic response, as well as the imprecision of the test methods available for determining protein and powder content. Ansell supports, on an interim basis, the alternative proposal by HIMA that there be a three tier labeling approach for protein content (50μg or less, 200 μg or less, and over 200 μg), until such time as a more meaningful measure of allergen levels is developed. Ansell also supports a two tier approach for powder content (meeting or exceeding the recommended powder limits established by ASTM for surgeon's gloves and patient examination gloves, respectively).

3. Labeling for Synthetic Gloves. FDA proposes that all powdered synthetic gloves be required to bear the statement "Caution: Glove powder is associated with adverse reactions." Ansell opposes this requirement based on the absence of evidence of significant adverse reactions from powder on synthetic gloves to justify requiring such a statement on their labeling.

FDA also proposes that synthetic gloves, as well as latex gloves be required to declare the amount of powder contained on the glove. Ansell does not oppose a recommended limit on the amount of powder contained on synthetic powdered gloves but it does oppose the requirement that the amount of powder on synthetic gloves be declared on the label. Ansell does not believe there is sufficient evidence that powder on synthetic gloves has significant adverse health effects to justify a labeling requirement. The company does not oppose a requirement that synthetic gloves exceeding the ASTM recommended powder limit be required to state that fact on the label.

D. Expiration Dating

FDA also proposes to require expiration dating on medical gloves based on data to support the integrity of the gloves throughout their claimed shelf life. Ansell does not oppose the requirement for expiration dating but points out that there will not be adequate data for many glove products because of the need to change processes to achieve the reduced powder and protein levels being recommended for these products if the agency accepts only real time shelf life data.

Ansell recommends that the agency state that expiration dates may be based on appropriate accelerated aging tests based on the Arrhenius formula so long as this data is backed up by real time data. Ansell points out that an ASTM Task Group has been established to consider and recommend appropriate test parameters for such accelerated aging testing of medical gloves and that a recent study by Huang and Chen concluded that such accelerated aging tests provide "an approximate worst case estimate of shelf life for medical gloves." Under the circumstances, FDA should allow reliance on such testing even if there are presently no study protocols for accelerated aging tests, which are predictive of glove shelf life.

FDA's draft Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves released on November 16, 1999 is a constructive

approach to this situation and the final regulations should be consistent with this approach.

E. Status of Glove Liners

Ansell notes that while the proposal itself is silent on the status of glove liners, the proposed "Medical Glove Guidance Manual" on page 3-6 states that glove liners will be classified the same as medical gloves, i.e. as Class II medical devices.

Ansell opposes this reclassification of glove liners because these products do not contain latex protein or donning powder and none of the reasons for reclassifying medical gloves apply to them. They should be allowed to remain Class I devices.

F. Recommended versus Required Limits

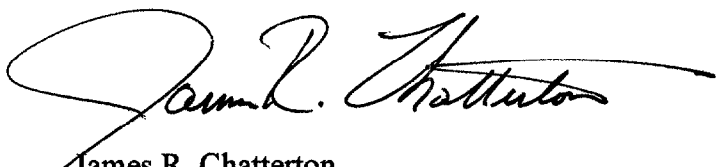
FDA has proposed recommended limits for both latex protein and glove powder and has asked whether its limits should be recommended or required limits. Ansell believes that only recommended limits are appropriate at this time. Not only may some manufacturers have difficulty in producing acceptable product meeting these limits, but the lack of precision of the tests for measuring protein and powder make it unreasonable for these limits to be required limits rather than recommended limits. Also, the fact that the measure of protein is not a reliable measure of allergen undermines any scientific basis for any required limitation of protein.

G. Timeframe for Implementation

Because the proposal will require both significant changes in processing of medical gloves and the re-labeling of most if not all glove products, Ansell supports a two year period for implementation. Ansell expects to implement the new recommended levels as quickly as possible for its own products but labeling changes involve serious logistical problems to implement and it is unreasonable to expect the industry to complete changes on so many products in less than a two year timeframe.

Respectfully submitted,

ANSELL PERRY



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